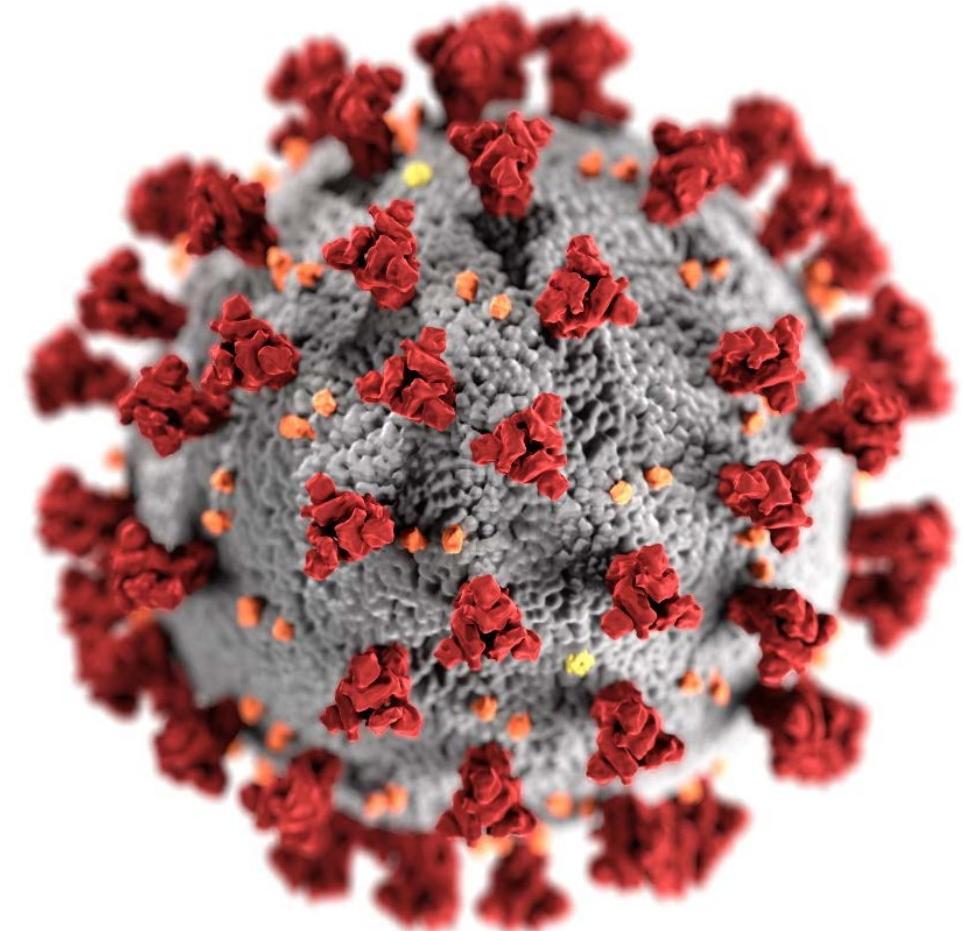


# Exhibit QQ

# COVID-19 Vaccines in Adults: Benefit-Risk Discussion

Hannah Rosenblum, MD  
ACIP Meeting  
July 22, 2021



[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

## Current COVID-19 vaccine policy

- Today's discussion will focus on the benefits and harms of COVID-19 vaccines in adults
- Three COVID-19 vaccines are recommended for persons aged 18 years and older in the United States under FDA's Emergency Use Authorization

# Benefits and risks by vaccine, age and sex in adults

**Benefits of COVID-19  
Janssen and mRNA  
vaccines in adults**

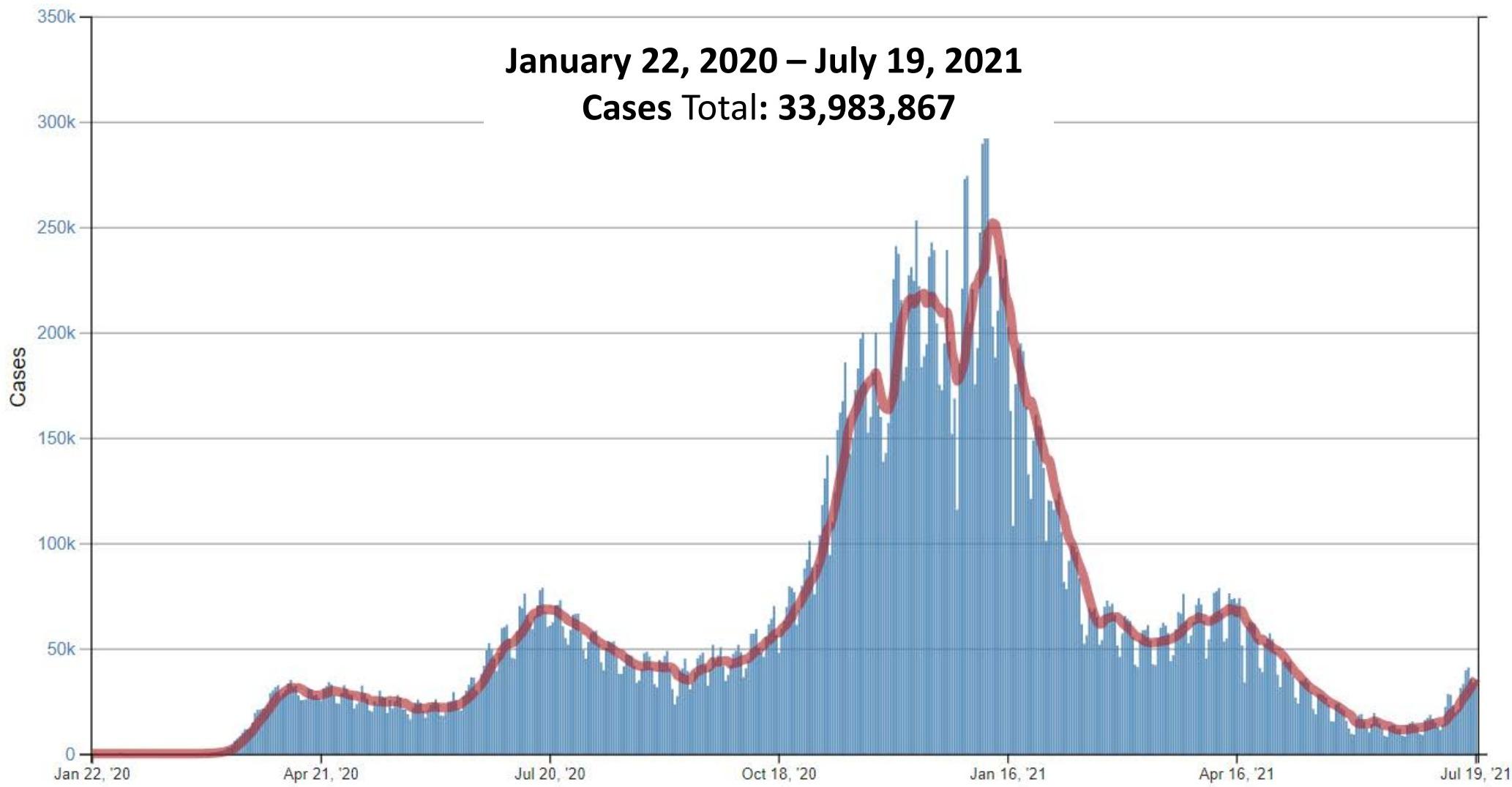


**Risk after COVID-19  
Janssen and mRNA  
vaccines in adults**

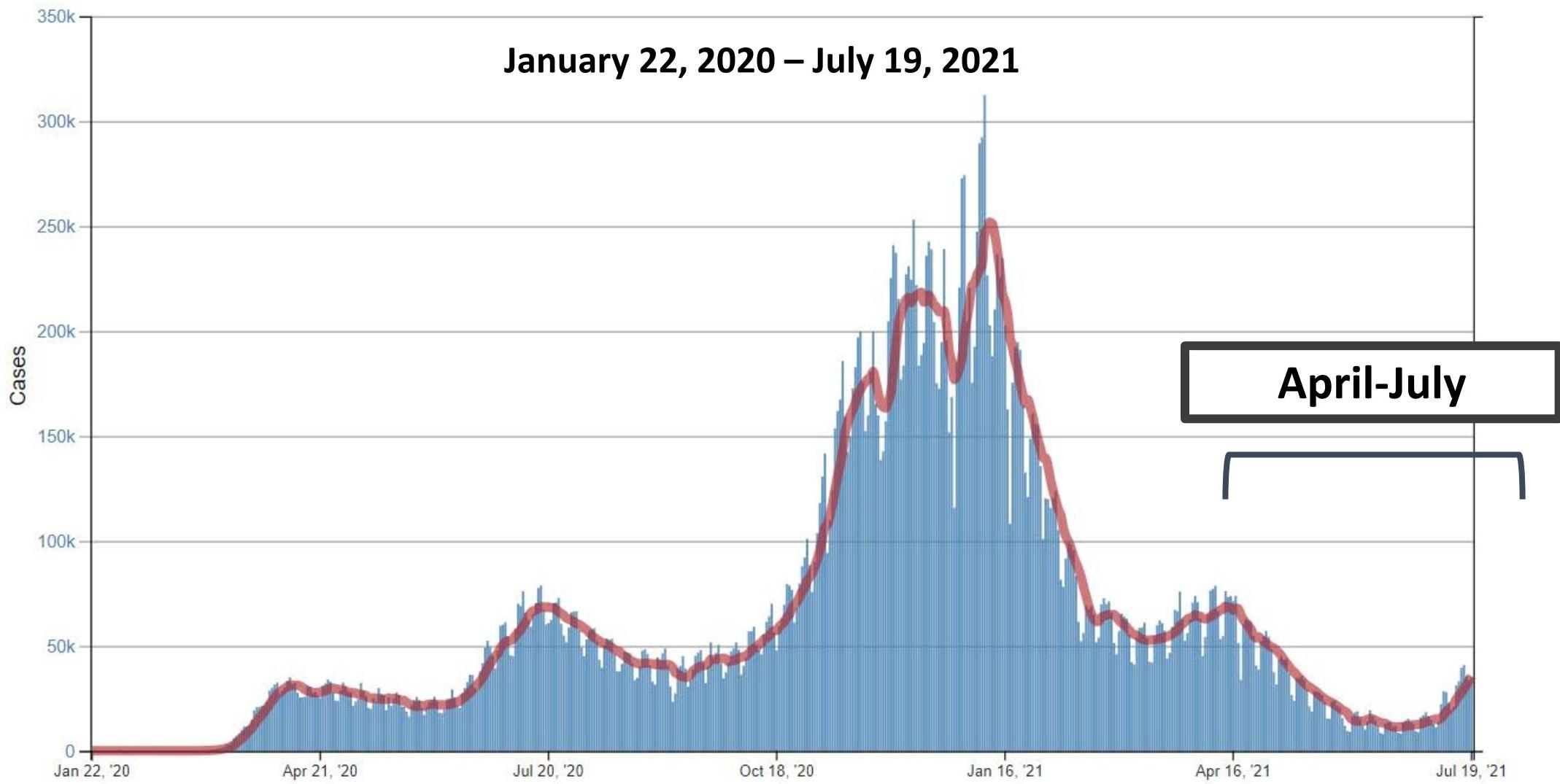
# COVID-19 vaccines in adults: Benefit-risk discussion

- Public health problem
  - Recent COVID-19 epidemiology in adults
  - Adverse events reported after vaccination
    - Guillain-Barre Syndrome (GBS)
    - Thrombosis with Thrombocytopenia Syndrome (TTS)
    - Myocarditis
- Benefit/Risk assessment
  - Benefits of Janssen vaccine
  - Risk of GBS after Janssen vaccine
  - Risk of TTS after Janssen vaccine
  - Benefits of mRNA vaccines
  - Risk of myocarditis after mRNA vaccines

# Trends in number of U.S. COVID-19 cases reported to CDC

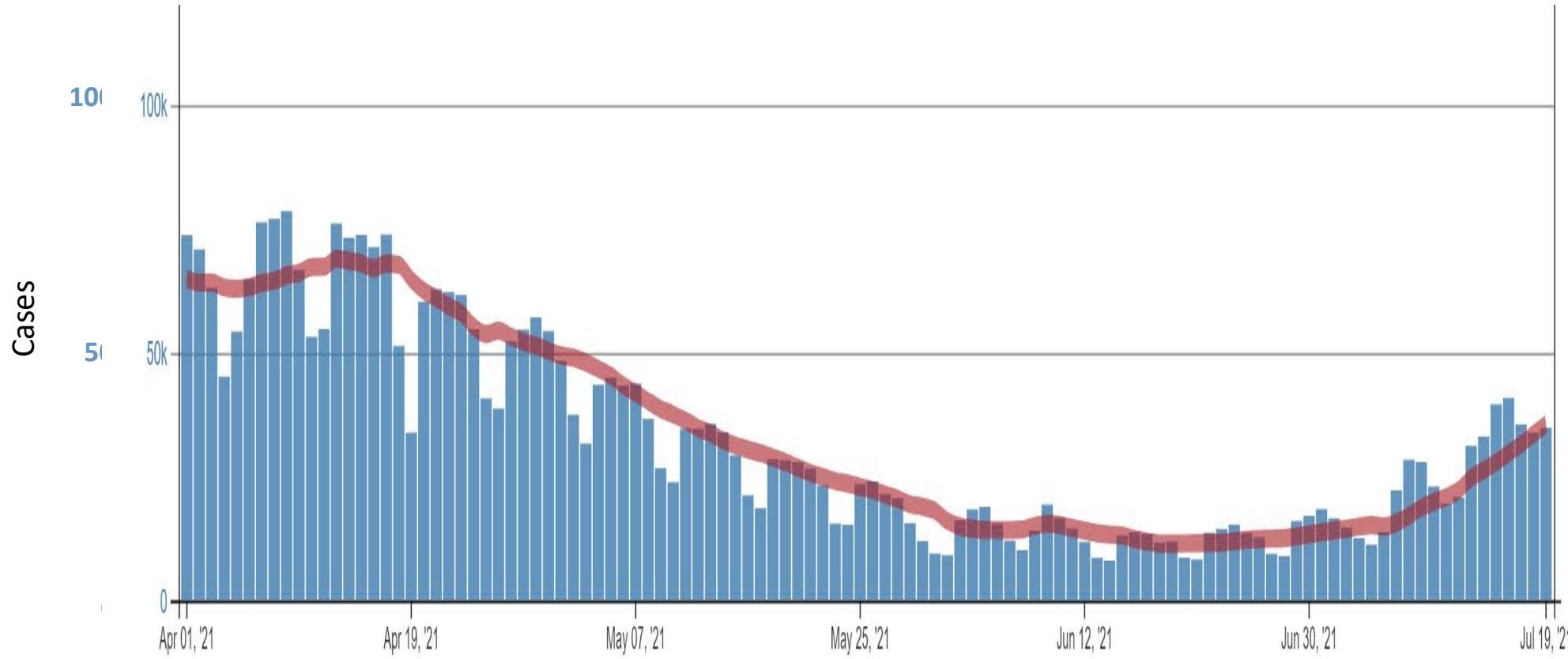


# Trends in number of U.S. COVID-19 cases reported to CDC



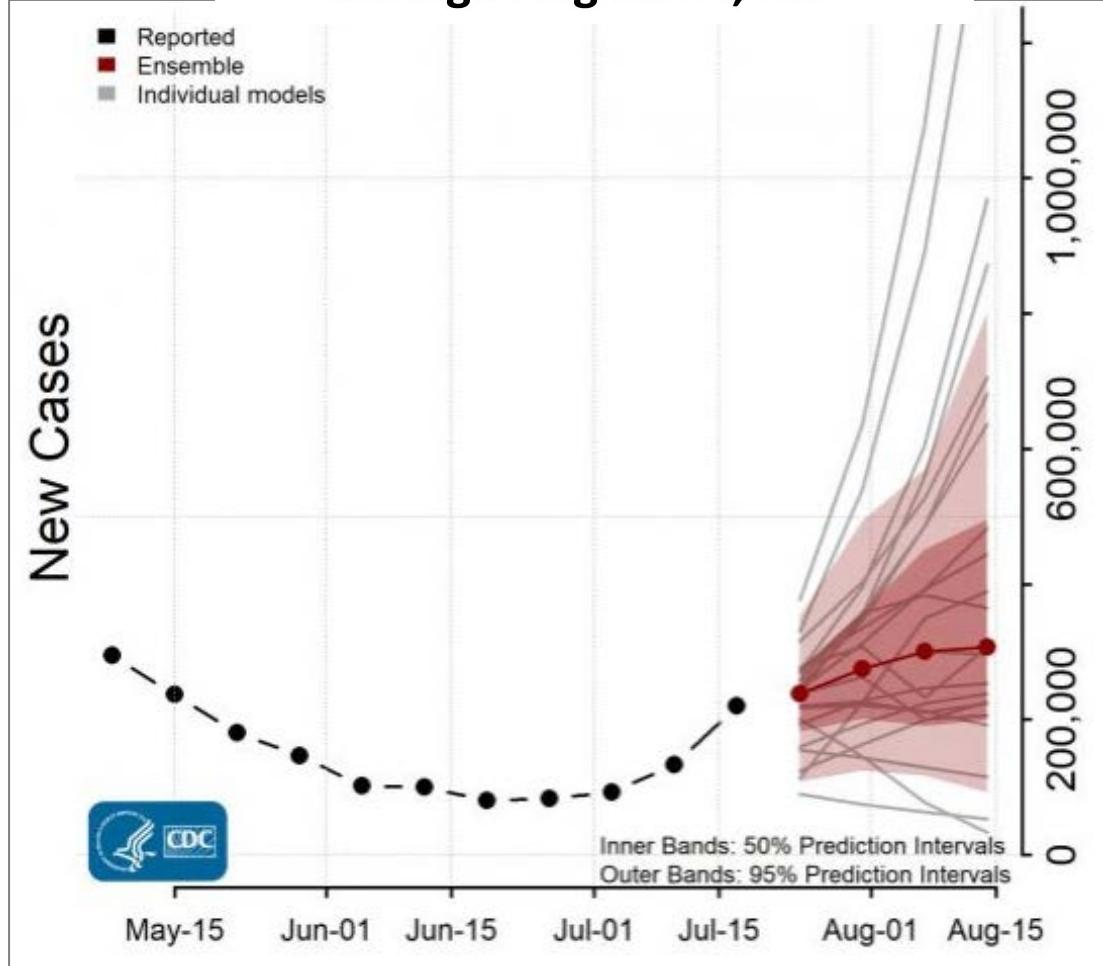
# Recent trends in number of U.S. COVID-19 cases

April 1, 2020 – July 19, 2021

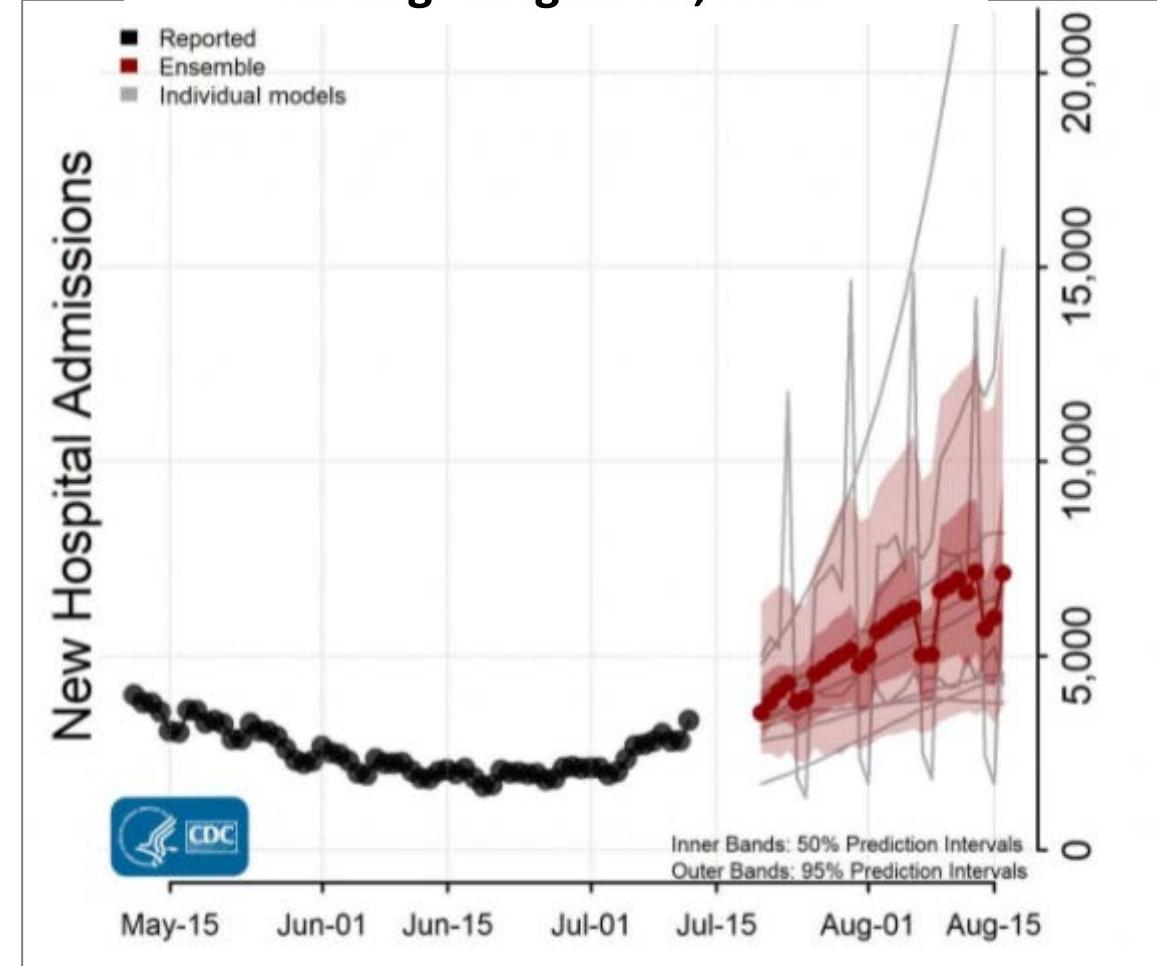


# Forecast of cases and hospitalizations for the next four weeks

New COVID-19 cases forecasted  
through August 14, 2021

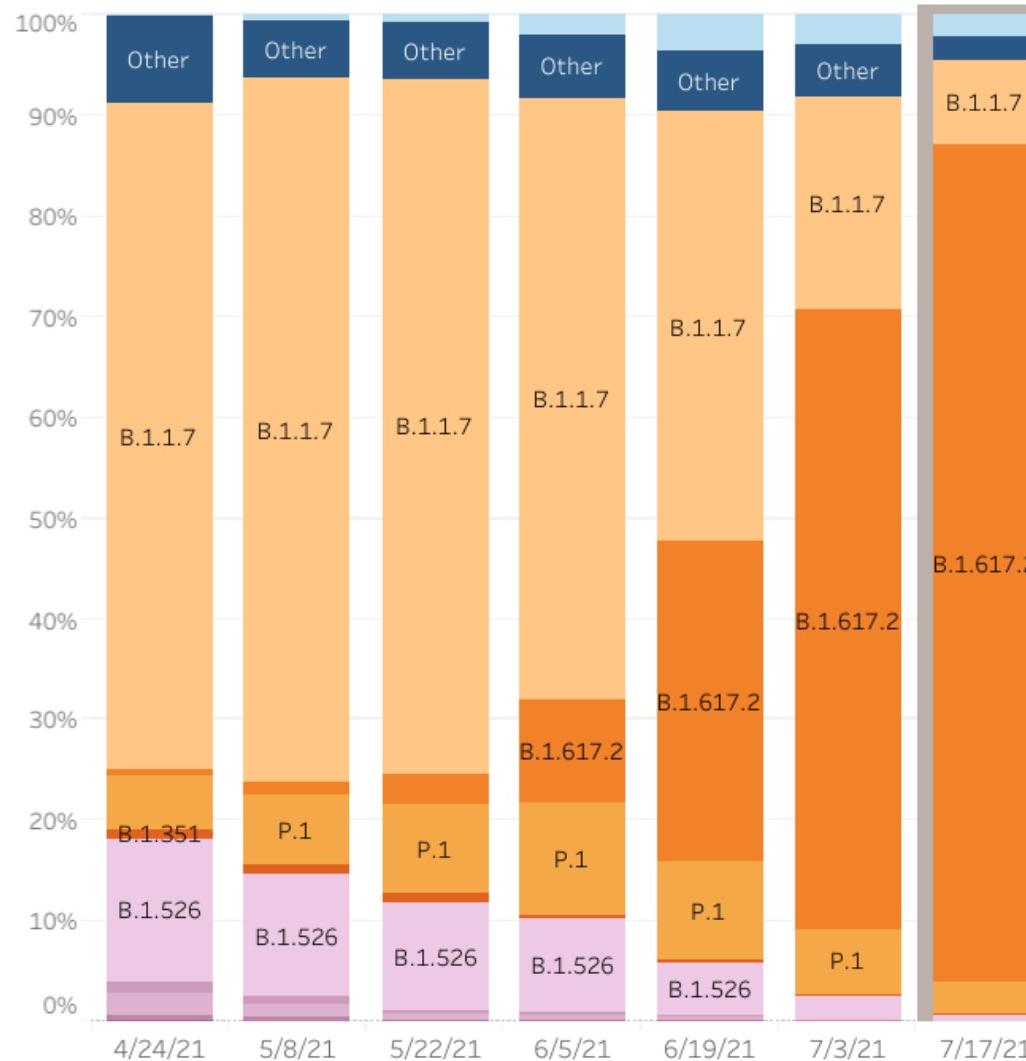


COVID-19 hospitalizations forecasted  
through August 16, 2021



# SARS-CoV-2 variants circulating in the United States

April 11 – July 17, 2021



Alpha (B.1.1.7): 8%

**Delta (B.1.617.2):  
83.2%**

Gamma (P.1): 3%

# Rare serious adverse events reported after COVID-19 vaccination

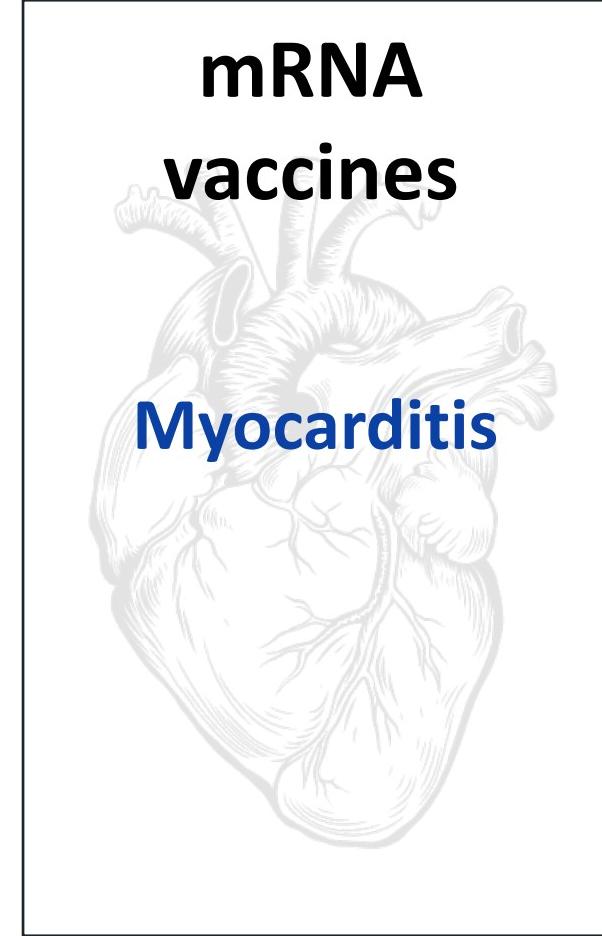
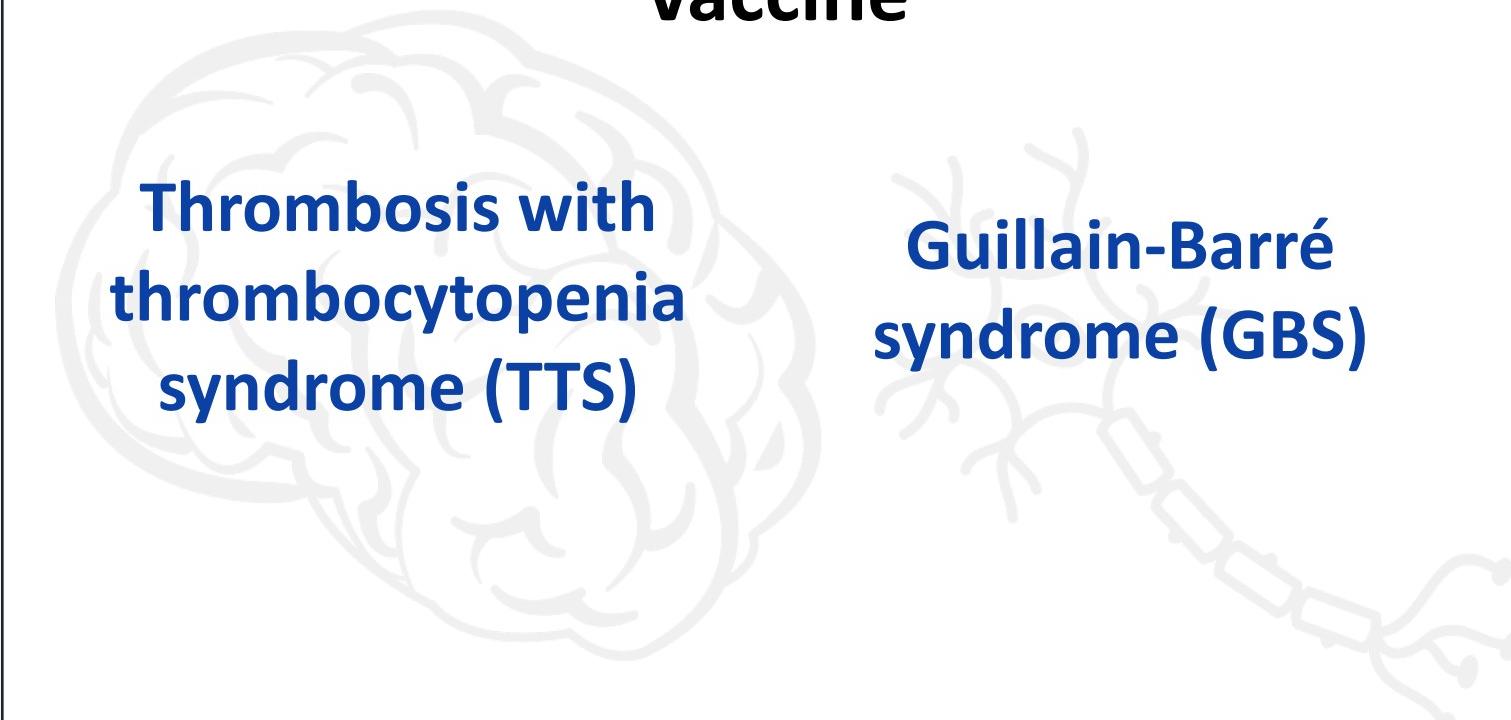
Janssen  
vaccine

Thrombosis with  
thrombocytopenia  
syndrome (TTS)

Guillain-Barré  
syndrome (GBS)

mRNA  
vaccines

Myocarditis



## Summary

- After a period of decline, COVID-19 cases and hospitalizations have begun to increase in recent weeks.
  - Variants continue to spread; Delta variant now found in >80% of cases in the United States
- Rare events have been observed after COVID-19 vaccination:
  - Janssen vaccine: TTS & GBS
  - mRNA vaccine: myocarditis

# Benefits and Harms of Janssen COVID-19 Vaccine



# Methods for assessment of benefit-risk balance – Janssen vaccine

## Benefits

- Expected protection provided per 1 million Janssen vaccine doses by age/sex calculated using:
  - Most recent case incidence, COVID-NET hospitalization & severity data (through June 19<sup>th</sup>)
  - VE (90%) for hospitalization
  - VE (66%) for COVID-19 symptomatic cases
  - 120-day period



# Methods for assessment of benefit-risk balance – Janssen vaccine

## Benefits

- Expected protection provided per 1 million Janssen vaccine doses by age/sex calculated using:
  - Most recent case incidence, COVID-NET hospitalization & severity data (through June 19<sup>th</sup>)
  - VE (90%) for hospitalization
  - VE (66%) for COVID-19 symptomatic cases
  - 120-day period

## Potential harms

- Estimated cases of **GBS** per 1 million Janssen vaccine doses, by age/sex using cases from VAERS through June 30, 2021
- Estimated cases of **TTs** per 1 million Janssen vaccine doses, by age/sex using cases reported to VAERS through July 8, 2021



## Benefits of the Janssen COVID-19 vaccine

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. Overall efficacy was **66%**
- Against **severe** outcomes:
  - Vaccine efficacy against COVID-19-associated **hospitalization**: **93%**
  - VE against **deaths** due to COVID-19: **100%**
- Persistence of antibody response & activity demonstrated against a variety of variants\*

# Potential Harms of the Janssen COVID-19 vaccine:

## Guillain-Barré Syndrome

- 12.6 million vaccine doses administered\* and 98 GBS cases as of June 30, 2021

	Females n= 37			Males n=61		
Age group	Cases	Doses admin	Reporting rate <sup>†</sup>	Cases	Doses admin	Reporting rate <sup>†</sup>
<b>18-29 years old</b>	1	1,037,996	1.0 per million	3	1,258,963	2.4 per million
<b>30-49 years old</b>	13	1,957,663	6.6 per million	18	2,407,430	7.5 per million
<b>50-64 years old</b>	14	1,888,715	7.4 per million	<b>33</b>	<b>2,115,411</b>	<b>15.6 per million</b>
<b>65+ years old</b>	9	1,037,996	8.7 per million	7	932,764	7.5 per million

\* Source of doses administered: FDA, through June 30, 2021; Some age- and sex-specific dose administered data were imputed

<sup>†</sup> Reporting rate = GBS cases per 1 million Janssen COVID-19 vaccine doses administered

GBS = Guillain-Barré Syndrome

# Potential Harms of the Janssen COVID-19 vaccine:

## Thrombosis with Thrombocytopenia Syndrome

- 12.5 million vaccine doses administered\* and 38 confirmed TTS cases as of July 8, 2021

	Females n= 28			Males n=10		
Age group	Cases	Doses admin	Reporting rate <sup>†</sup>	Cases	Doses admin	Reporting rate <sup>†</sup>
18-29 years old	4	946,358	4.2 per million	3	1,281,479	2.3 per million
30-49 years old	17	1,934,574	8.8 per million	4	2,440,773	1.6 per million
50-64 years old	7	1,865,372	3.8 per million	3	2,130,473	1.4 per million
65+ years old	0	1,028,190	0.0 per million	0	943,098	0.0 per million

\* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations> through July 8, 2021; Some age- and sex-specific doses administered data were imputed

<sup>†</sup> Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

TTS=Thrombosis with Thrombocytopenia Syndrome

# Estimated predicted COVID-19 cases prevented vs. GBS cases for every million Janssen vaccinations over 120 days

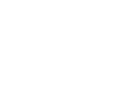
## Females 18–29 Years

-  **8,900** COVID-19 cases prevented
-  **700** hospitalizations prevented
-  **50** ICU admissions prevented
-  **5** deaths prevented

---

**1 GBS case**

## Males 18–29 Years

-  **6,600** COVID-19 cases prevented
-  **300** hospitalizations prevented
-  **60** ICU admissions prevented
-  **3** deaths prevented

---

**2 GBS cases**

# Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

## Females 18–29 Years

-  **8,900** COVID-19 cases prevented
-  **700** hospitalizations prevented
-  **50** ICU admissions prevented
- 5** deaths prevented

---

**1 GBS case  
4-5 TTS cases**

## Males 18–29 Years

-  **6,600** COVID-19 cases prevented
-  **300** hospitalizations prevented
-  **60** ICU admissions prevented
- 3** deaths prevented

---

**2 GBS cases  
2-3 TTS cases**

# Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

## Females 30–49 Years

-  **10,100** COVID-19 cases prevented
-  **900** hospitalizations prevented
-  **140** ICU admissions prevented
- 20** deaths prevented

**6-7 GBS cases  
8-10 TTS cases**

## Males 30–49 Years

-  **7,600** COVID-19 cases prevented
-  **650** hospitalizations prevented
-  **150** ICU admissions prevented
- 25** deaths prevented

**7-8 GBS cases  
1-2 TTS cases**

# Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

## Females 50–64 Years

-  **12,100** COVID-19 cases prevented
-  **1,600** hospitalizations prevented
-  **350** ICU admissions prevented
- 120** deaths prevented

**7-8 GBS cases**

**3-4 TTS cases**

## Males 50–64 Years

-  **10,100** COVID-19 cases prevented
-  **1,800** hospitalizations prevented
-  **480** ICU admissions prevented
- 140** deaths prevented

**14-17 GBS cases**

**1-2 TTS cases**

# Estimated predicted COVID-19 cases prevented vs. GBS & TTS cases for every million Janssen vaccinations over 120 days

## Females 65+ Years

-  **29,000** COVID-19 cases prevented
-  **5,900** hospitalizations prevented
-  **1,250** ICU admissions prevented
- 840** deaths prevented

**8-10 GBS cases  
0 TTS cases**

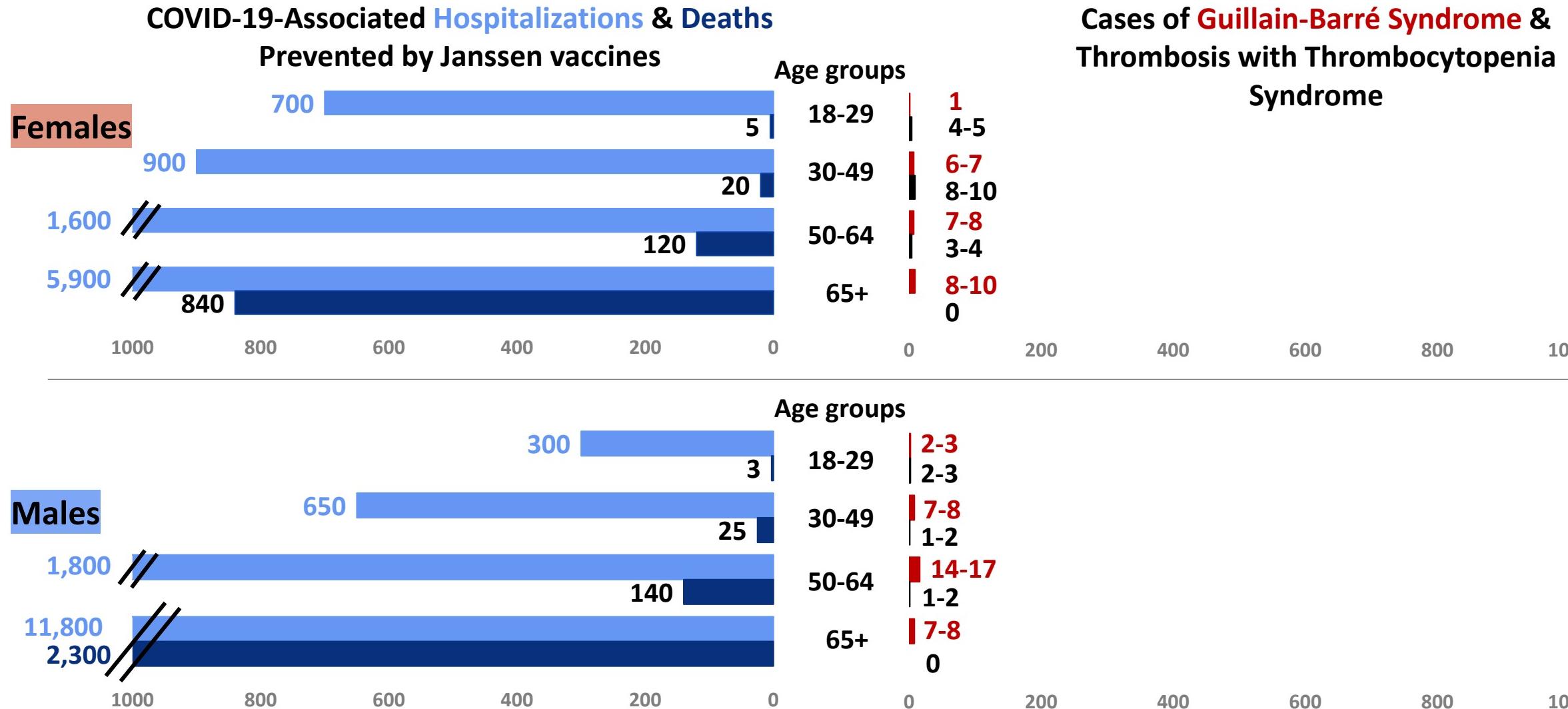
## Males 65+ Years

-  **36,600** COVID-19 cases prevented
-  **11,800** hospitalizations prevented
-  **3,300** ICU admissions prevented
- 2,300** deaths prevented

**7-8 GBS cases  
0 TTS cases**

# Benefits and risks after Janssen vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021



# Benefits and Harms of mRNA COVID-19 Vaccines



# Methods for assessment of benefit-risk balance – mRNA COVID-19 vaccines in adults

## Benefits

- Expected protection provided per 1 million mRNA vaccine doses using:
  - Most recent case incidence, COVID-NET hospitalization and severity data (through June 19<sup>th</sup>)
  - VE for hospitalization (95%)
  - VE for COVID-19 symptomatic cases (95%)
  - 120-day period

## Potential harms

- Estimated cases of **myocarditis** per 1 million second doses of mRNA COVID-19 vaccine, by age/sex using data from VAERS through June 30, 2021



## Benefits of mRNA vaccines

- Clinical trial data demonstrated high efficacy against symptomatic, laboratory-confirmed COVID-19 among adults with both mRNA vaccines (Pfizer-BioNTech and Moderna)
  - Overall efficacy was **94-95%**
  - Vaccine efficacy against COVID-19 associated hospitalization was **89-100%**
- Persistence of antibody response & activity demonstrated against a variety of variants\*

# Potential Harms of the mRNA COVID-19 vaccines:

## Myocarditis

- 141 million 2<sup>nd</sup> mRNA vaccine doses administered\* and 497 myocarditis cases as of June 30, 2021 in age 18+

	<b>Females n= 105</b>			<b>Males n= 392</b>		
<b>Age group</b>	<b>Cases</b>	<b>Doses admin</b>	<b>Reporting rate<sup>†</sup></b>	<b>Cases*</b>	<b>Doses admin</b>	<b>Reporting rate<sup>†</sup></b>
<b>18-29 years old<sup>§</sup></b>	<b>34</b>	<b>10,491,212</b>	<b>3.2 per million</b>	<b>248</b>	<b>10,212,647</b>	<b>24.3 per million</b>
<b>30-49 years old</b>	<b>38</b>	<b>20,875,708</b>	<b>1.8 per million</b>	<b>117</b>	<b>20,154,577</b>	<b>5.8 per million</b>
<b>50-64 years old</b>	<b>23</b>	<b>19,714,915</b>	<b>1.2 per million</b>	<b>15</b>	<b>18,514,388</b>	<b>0.8 per million</b>
<b>65+ years old</b>	<b>10</b>	<b>22,274,470</b>	<b>0.4 per million</b>	<b>12</b>	<b>19,518,324</b>	<b>0.6 per million</b>

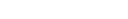
\*Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; some age- and sex-specific doses administered data were imputed

<sup>†</sup>Reporting rate = myocarditis cases per 1 million mRNA COVID-19 mRNA second vaccine doses administered

<sup>§</sup>Myocarditis cases in 18-29-year-olds are confirmed cases meeting CDC's case definition

# Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

## Females 18-29 Years

-  **12,800** COVID-19 cases prevented
-  **750** hospitalizations prevented
-  **50** ICU admissions prevented
-  **5** deaths prevented

**3-4 myocarditis cases** 

## Males 18-29 Years

-  **9,600** COVID-19 cases prevented
-  **300** hospitalizations prevented
-  **60** ICU admissions prevented
-  **3** deaths prevented

**22-27 myocarditis cases** 

# Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

## Females 30-49 Years

-  **14,600** COVID-19 cases prevented
-  **950** hospitalizations prevented
-  **140** ICU admissions prevented
- 20** deaths prevented

## Males 30-49 Years

-  **11,000** COVID-19 cases prevented
-  **700** hospitalizations prevented
-  **160** ICU admissions prevented
- 25** deaths prevented

**1-2** myocarditis cases 

**5-6** myocarditis cases 

# Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

## Females 50-64 Years

-  **17,500** COVID-19 cases prevented
-  **1,700** hospitalizations prevented
-  **375** ICU admissions prevented
- 125** deaths prevented

## Males 50-64 Years

-  **14,700** COVID-19 cases prevented
-  **1,900** hospitalizations prevented
-  **500** ICU admissions prevented
- 150** deaths prevented

**1** myocarditis case 

**1** myocarditis case 

# Estimated predicted COVID-19 cases prevented vs. myocarditis cases for every million mRNA vaccinations over 120 days

## Females 65+ Years

-  **32,000** COVID-19 cases prevented
-  **6,200** hospitalizations prevented
-  **1,300** ICU admissions prevented
- 900** deaths prevented

## Males 65+ Years

-  **52,700** COVID-19 cases prevented
-  **12,500** hospitalizations prevented
-  **3,500** ICU admissions prevented
- 2,400** deaths prevented

**<1** myocarditis case

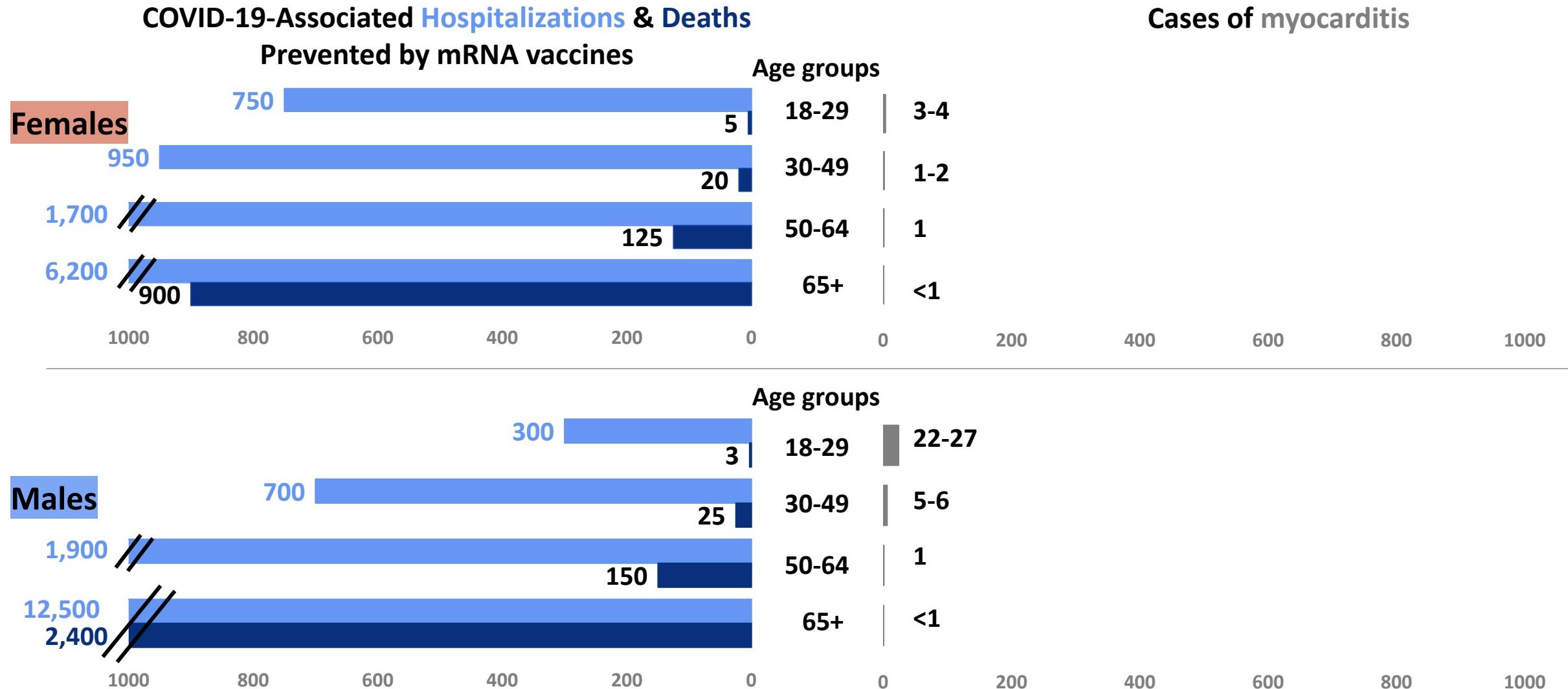


**<1** myocarditis case



# Benefits and risks after mRNA vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021



# Summary

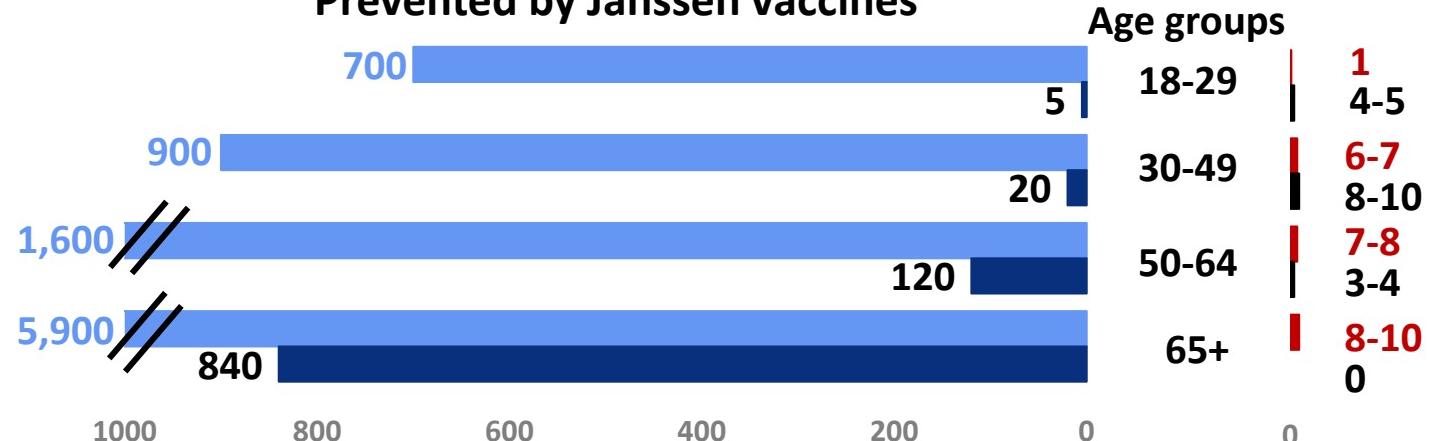


# Benefits and risks after COVID-19 vaccine, by age group- females

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021

## COVID-19-Associated Hospitalizations and Deaths

### Prevented by Janssen vaccines

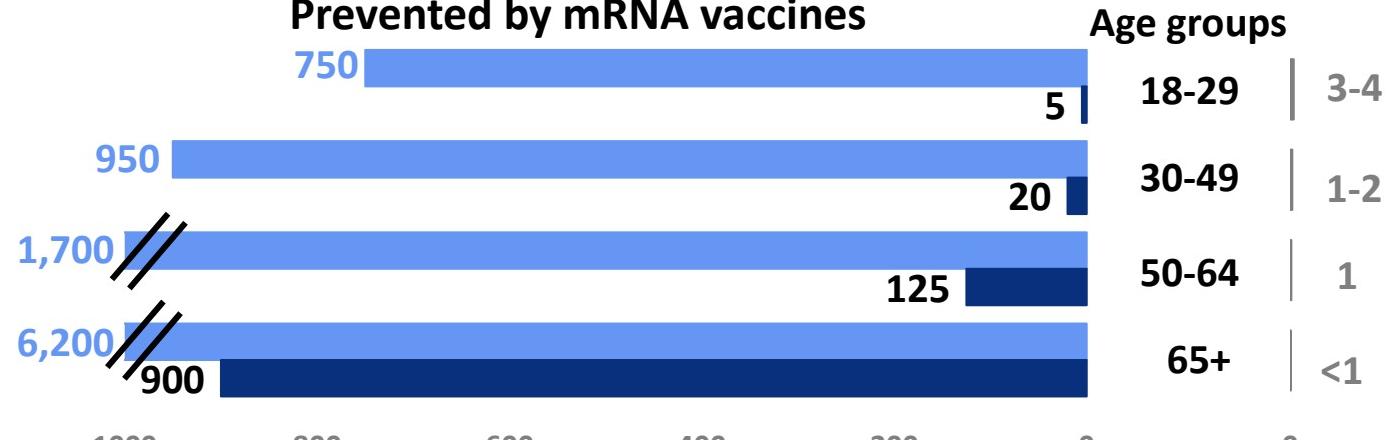


## Cases of Guillain-Barré Syndrome &

### Thrombosis with Thrombocytopenia Syndrome

## COVID-19-Associated Hospitalizations and Deaths

### Prevented by mRNA vaccines



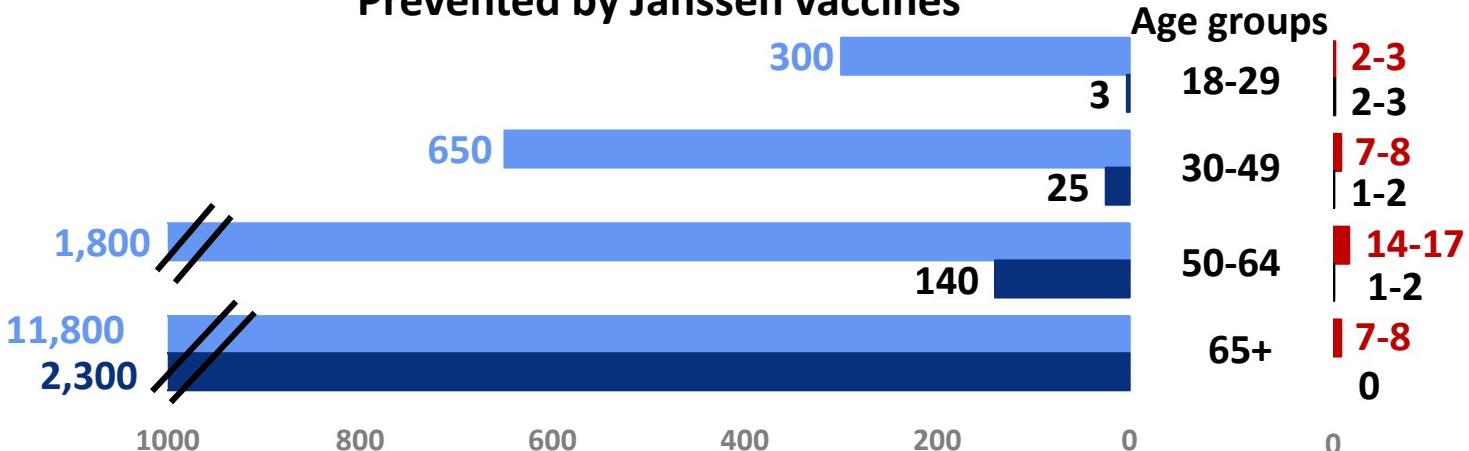
## Cases of myocarditis

# Benefits and risks after COVID-19 vaccine, by age group- males

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021

## COVID-19-Associated Hospitalizations and Deaths

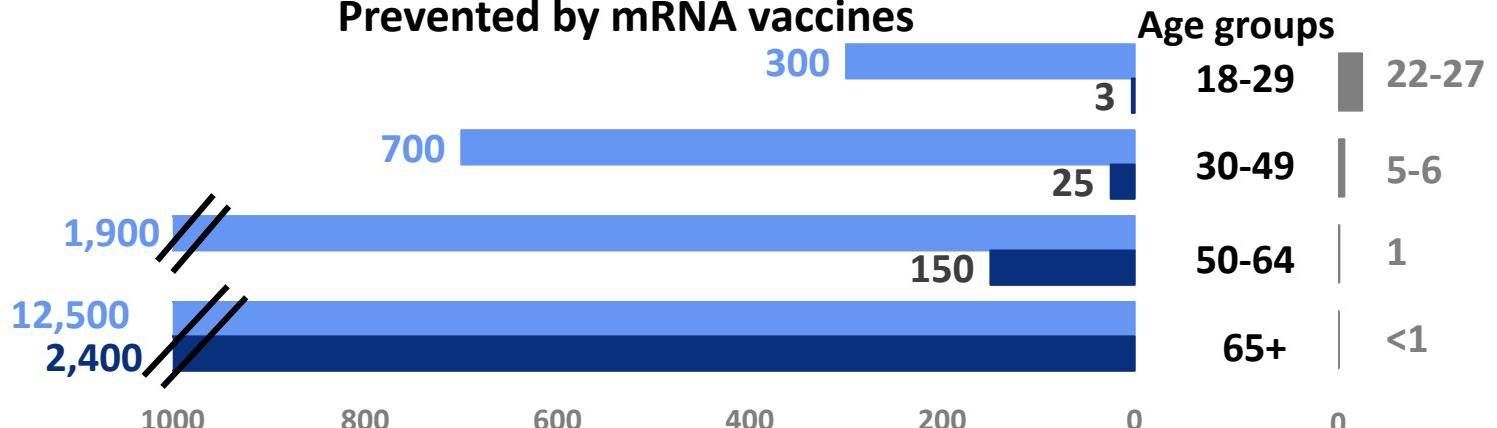
### Prevented by Janssen vaccines



## Cases of Guillain-Barré Syndrome & Thrombosis with Thrombocytopenia Syndrome

## COVID-19-Associated Hospitalizations and Deaths

### Prevented by mRNA vaccines



## Cases of myocarditis

# Benefits and risks after COVID-19 vaccine, by age group & sex

For every million doses of vaccine given with US exposure risk and hospitalization rates from June 19, 2021

	Janssen COVID-19 vaccine						mRNA COVID-19 vaccines			
Age	Prevented COVID-19 Outcomes			GBS Cases	TTS Cases		Prevented COVID-19 Outcomes			Myocarditis Cases
	Hospitalization	ICU	Death				Hospitalization	ICU	Death	
<b>FEMALES</b>										
18-29 years	700	50	5	1	4-5		750	50	5	3-4
30-49 years	900	140	20	6-7	8-10		950	140	20	1-2
50-64 years	1600	350	120	7-8	3-4		1,700	375	125	1
65+ years	5,900	1250	840	8-10	0		6,200	1300	900	<1
<b>MALES</b>										
18-29 years	300	60	3	2	2-3		300	60	3	22-27
30-49 years	650	150	25	7-8	1-2		700	160	25	5-6
50-64 years	1,800	480	140	14-17	1-2		1,900	500	150	1
65+ years	11,800	3300	2300	7-8	0		12,500	3500	2400	<1

# Potential harms reported overall after COVID-19 vaccination

## Janssen vaccine

**Thrombosis with  
thrombocytopenia  
syndrome:**

**3.0** cases  
per million doses  
among adults

**Guillain-Barré  
syndrome:**

**7.8** cases  
per million doses  
among adults

## mRNA vaccines

**Myocarditis:**

**3.5** cases  
per million doses  
among adults

- Risk for each potential harm varies by age and by sex

## Limitations of benefit-risk estimates

- Benefits of vaccination likely even greater than shown
  - Model uses current case estimates; does not account for underreporting or rising case counts
  - Benefits are estimated over 120 days following vaccination, but protection likely lasts longer
  - Does not account for post-COVID-19 conditions
- Some hospitalizations (COVID-NET) may be related to diagnoses other than COVID-19
- Vaccine efficacy from clinical trials rather than real-world data
- Crude numbers of potential harms were used for some estimates

# Benefit-risk interpretation and summary

- An assessment of the individual benefits and individual risks of vaccination is an important tool to help inform vaccination policy
- **This assessment demonstrates that the benefits of COVID-19 vaccination far outweigh the potential risks**
- The relative balance of benefits-risks varies by age/sex



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- Lauri Markowitz
- Melinda Wharton
- Vaccine Safety Team
- Epidemiology and Surveillance Task Force
- Vaccine Task Force



For more information, contact CDC  
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TTY: 1-888-232-6348   [www.cdc.gov](http://www.cdc.gov)

# Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

